

10/587389

PATENT Case No. ITR0048YP

IAP11 Rec'd PCT/PTO 25 JUL 2006

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Stefano Colloca, Alfredo Nicosio, Elisabetta  
Sproeno, Agostino Cirillo, Bruno Bruni Ercole,  
Annalisa Meola

Serial No. To be assigned

Filed: Herewith

For: CHIMPANZEE ADENOVIRUS VACCINE CARRIERS

Art Unit: To be assigned

Examiner: To be assigned

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

## EXPRESS MAIL CERTIFICATE

DATE OF DEPOSIT July 24, 2006  
EXPRESS MAIL NO. EV321988911US  
I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS  
BEING DEPOSITED WITH THE UNITED STATES POSTAL  
SERVICE AS EXPRESS MAIL "POST OFFICE TO ADDRESSEE"  
ON THE ABOVE DATE IN AN ENVELOPE ADDRESSED TO  
COMMISSIONER FOR PATENTS, P.O. BOX 1450,  
ALEXANDRIA, VIRGINIA 22313-1450.  
MAILED BY Sandra Zeller  
DATE July 24, 2006

**10/587389** PATENT Case No. ITR0048YP  
**IAP11 Rec'd PCT/PTO 25 JUL 2006**  
**INFORMATION DISCLOSURE STATEMENT**

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Patricia L. Chisholm

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 45,822

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-5738

Date: July 24, 2006

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE

## STATEMENT BY APPLICANT

*(use as many sheets as necessary)*

**COMPLETE IF KNOWN****Application Number****Filing Date****First Named Inventor**

Colloca, Stefano

## Group Art Unit

**To be assigned**

Examiner Name

To be assigned

Sheet

1

of

3

Attorney Docket Number

ITR0048YP

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
	C	WO	05001103		Trustees of University of Pennsylvania	06/15/2004
	D	WO	0346124		Trustees of University of Pennsylvania	06/05/2003
	E	WO	9810087		Trustees of University of Pennsylvania	09/04/1997
	F	WO	03000851		Trustees of University of Pennsylvania	06/20/2002
	G	WO	03000283		Wistar Institute of Anatomy & Biology	01/03/2003

**Examiner  
Signature**

Date  
Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., -7/12/2005

Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE</b>  <b>STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>COMPLETE IF KNOWN</b>		
			Application Number		
			Filing Date		
			First Named Inventor	Colloca, Stefano	
			Group Art Unit	To be assigned	
			Examiner Name	To be assigned	
Sheet	2	of	3	Attorney Docket Number	ITR0048YP

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	H	ROY, SOUMITRA, ET AL., Virology, "Complete nucleotide sequences and genome organization of four chimpanzee adenoviruses", Vol. 324, pages 361-372, 2004.
	I	WIGAND, R., ET AL., Intervirology, "Chimpanzee adenoviruses are related to four subgenera of human adenoviruses", Vol. 30, pages 1-9, 1989.
	J	FARINA, SETVEN F., ET AL., Journal of Virology, "Replication-defective vector based on a chimpanzee adenovirus", Vol. 75, No. 23, pages, 11603-11613, 2001.
	K	FITZGERALD, JULIE C., ET AL., The Journal of Immunology, "A simian replication-defective adenoviral recombinant vaccine to HIV-1 gag", Vol. 170, pages 1416-1422, 2003.
	L	GALL, JASON G.D., ET AL., Journal of Virology, "Construction and characterization of hexon-chimeric adenoviruses: specification of adenovirus serotype", Vol. 72, No. 12, pages 10260-10264, 1998.
	M	WU, HONGJU, ET AL., Journal of Virology, "Construction and characterization of adenovirus serotype 5 packaged by serotype 3 hexon", Vol. 76, No. 24, pages 12775-12782, 2002.
	N	SIEMENS, ROBERT D., ET AL., The Journal of Immunology", Vol. 166, pages 731-735, 2001.
	O	CRAWFORD-MIKSZA, LETA, ET AL., Journal of Virology, Vol. 70, pages 1836-1844, 1996.
	P	MASTRANGELI, ANDREA, ET AL., Human Gene Therapy, ""Sero-switch" Adenovirus-mediated <i>In vivo</i> gene transfer: circumvention of anti-adenovirus humoral immune defenses against repeat adenovirus vector administration by changing the adenovirus serotype:", Vol. 7, pages 79-97, 1996.
	Q	COHEN, CHRISTOPHER, J., ET AL., Journal of General Virology, "Chimpanzee adenovirus CV-68 adapted as a gene delivery vector interacts with the coxsackievirus and adenovirus receptor", Vol. 83, pages 151-155, 2002.
	R	BASNIGHT, MINT JR., ET AL., American Journal of Epidemiology, "Characterization of four new adenovirus serotypes isolated from chimpanzee tissue explants", Vol. 94, No. 2, 1971.
	S	XIANG, ZHIQUAN, ET AL., Journal of Virology, "Novel, chimpanzee serotype 68-based adenoviral vaccine carrier for induction of antibodies to a transgene product", Vol. 76, No. 6, pages 2667-2675, 2002.
	T	WILLIMZIK, H.-F., ET AL., Intervirology, "Immunological relationship among adenoviruses of human, simians, and nonprimates as determined by the neutralization test", Vol. 15, pages 28-36, 1981.
	U	ROVERO, STEFANIA, ET AL., The Journal of Immunology, "DNA vaccination against rat Her-2/Neu p185 more effectively inhibits carcinogenesis than transplantable carcinomas in transgenic BALB/c mice <sup>1,2</sup> ", Vol. 165, pages 5133-5142, 2000.
	V	ROY, SOUMITRA, ET AL., Human Gene Therapy, "Characterization of a family of chimpanzee adenoviruses and development of molecular clones for gene transfer vectors", Vol. 15, pages 519-530, 2004.

Examiner Signature	Date Considered
--------------------	-----------------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., -7/12/2005

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE**  
**STATEMENT BY APPLICANT**

*(use as many sheets as necessary)*

**COMPLETE IF KNOWN**

Application Number

**Filing Date****First Named Inventor**

Colloca, Stefano

Group Art Unit

To be assigned

Examiner Name

To be assigned

Sheet

2

of

3

Attorney Docket Number

ITR0048YP

## NON PATENT LITERATURE DOCUMENTS

Examiner  
Initials\*Cite  
No.

**Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.**

W

vaccine by heterologous priming-boosting with novel adenoviral vectors based on different serotypes", Vol. 13, pages 1088-1096, 2006.

**X**

PINTO, ARGUINALDO R., ET AL., The Journal of Immunology, "Induction of CD8<sup>+</sup> T cells to an HIV-1 antigen through a prime boost regimen with heterologous E1-deleted adenoviral vaccine carriers", Vol. 171, pages 6774-6779, 2003.

Examiner  
Signature

Date  
Considered

\*Examiner. Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. Computer generated form \* IDS Form\* (IDS Folder), Merck & Co., Inc., -7/12/2005